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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/163,089	09/29/1998	IAN F. C. MCKENZIE	5036-1	9586

22442 7590 04/26/2004

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/14
Office Action Summary

Application No.

09/163,089

Applicant(s)

MCKENZIE ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-17,19-21,24-26,38 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-17,19-21,24-26,38 and 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed on 11-25-03 are acknowledged. Claims 71-72 have been added. Claims 1, 3-17, 19-21, 24-26, 38 and 70-72 are pending and currently under examination.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-17, 19-21, 24-26, 38 and 70-72 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office action in the rejection of claims 1, 3-17, 19-21, 24-26, 38 and 70. The specification, while being enabling for immunoregulatory compositions comprising mannose receptor bearing cells, and a conjugate comprising MUC1 (antigen) and a carbohydrate polymer comprising mannose, wherein said carbohydrate polymer is a fully oxidized carbohydrate polymer comprising free aldehydes, does not reasonably provide enablement for immunoregulatory compositions comprising mannose bearing cells and a conjugate comprising any antigen and a carbohydrate polymer comprising mannose, wherein said carbohydrate polymer is a fully oxidized polymer comprising free aldehydes.

Applicant argues:

1. Applicants have provided evidence that at least two different antigens can be used with the claimed conjugate and composition which, when administered *in vivo* to an animal, elicits an antigen specific immune response.
2. The mechanism of enhancing the immune response is provided by the constant factors in the composition of the mannose receptor bearing cells and the oxidized carbohydrate polymer not the specific antigen.
3. The data of Davis et al. supports the predictability of the use of the claimed composition with any suitable immunizing agent.
4. Applicants are in the process of preparing additional data showing the use of the instant invention comprising yet another antigen.
5. Applicant's have demonstrated that at least two different cell types can be successfully used in the composition of the invention.
6. Applicants submit that any mannose receptor bearing cells that are capable of delivering an antigen to the MHC class I pathway for MHC class I antigen presentation will be suitable for use in the instant invention.
7. The composition comprising CRIPTO and dendritic cells (as disclosed in the declaration of Dr. Pietersz) was administered to mice *in vivo* and hence demonstrated its *in vivo* efficacy.
8. Since the Declaration by Dr. Pietersz states that the conjugate of manna-Cripto was "prepared as described in the present application", it was assumed that it would be understood that the mannan was fully oxidized since oxidized mannan was disclosed in the instant specification.

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Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to compositions comprising isolated mannose receptor-bearing cells **and** a conjugate comprising an antigen and a carbohydrate polymer comprising mannose, wherein said carbohydrate polymer is a fully oxidized carbohydrate polymer comprising free aldehydes. **The mannose receptor-bearing cells are a required component of said composition.**

With regard to Points 1-3 and Point 7, Applicant's arguments, as well as the paper by Davis et al., demonstrate the effects of the antigen-polymer conjugate only. Davis et al. disclose the *ex vivo* pulsing of macrophage cultures and the measurement (profiling) of cytokine production. The compositions of Davis et al. are not commensurate in scope with the instant invention since they utilize only an antigen-polymer conjugate. As stated previously, the mannose receptor-bearing cells are a required component of the claimed invention. Therefore, since Applicant's arguments do not address compositions that fall within the metes and bounds of the rejected claims, they are deemed non-persuasive. Moreover, the data presented in the Declaration by Dr. Pietersz is not representative of the full scope of the claims. Said data demonstrated the *ex vivo* pulsing of a single cell type (dendritic cells) utilizing a single antigen (CRIPTO) and the ability of splenocytes taken from mice immunized with said pulsed cells to produce γ IFN in an *in vitro* assay. Said data is not commensurate in scope with the claimed invention since the antigen-polymer conjugate was removed from the pulsed dendritic cells prior to administration to the mice (see page 2 of Declaration).

With regard to Point 4, since no data was provided in a timely manner, Applicant's assertion regarding what said data demonstrates is given no weight.

In response to Point 6, it is noted that the features upon which applicant relies (i.e., that the mannose receptor bearing cells must be capable of MHC class I antigen presentation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regard to Point 8, since the specification discloses conjugates comprising fully oxidized mannose or partially reduced mannose. Consequently, one could not conclude that the conjugate utilized by Dr. Pietersz was commensurate in scope to the instant invention based on the statement that “manna-Cripto was prepared as described in the present application”.

New Claim Objections

Claim 71 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 70. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Mannan is a polymer of mannose.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

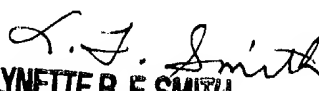
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
April 21, 2004


LYNETTE R. F. SMITH
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